ORAL ARGUMENT NOT YET SCHEDULED

No. 22-1076

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

FONTEM US, LLC,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

On Petition for Review of a Final Marketing Denial Order
by the U.S. Food and Drug Administration

BRIEF FOR RESPONDENT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), counsel certifies as follows:

A. Parties and Amici. Petitioner is Fontem US, LLC. Respondent is the U.S. Food and Drug Administration (FDA). No other parties or amici appeared in the agency proceeding.

B. Rulings Under Review. The ruling under review is a marketing denial order issued by FDA on April 8, 2022.

C. Related Cases. This case has not previously been before this Court or any other court. Counsel is not aware of any related cases within the meaning of Circuit Rule 28(a)(1)(C).

s/ *Garrett Coyle*
GARRETT COYLE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Regulations

Other Authorities

GLOSSARY

Act	Family Smoking Prevention and Tobacco Control Act
AR	Administrative Record
FDA	United States Food and Drug Administration
JA	Joint Appendix

INTRODUCTION

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or Act) makes it unlawful for a manufacturer to market a "new tobacco product" — defined as a tobacco product that was not on the market as of February 15, 2007 — without authorization from the U.S. Food and Drug Administration (FDA). The Act requires FDA to deny an application to market a new tobacco product unless FDA finds that marketing the product would be "appropriate for the protection of the public health," considering "the risks and benefits to the population as a whole," based on "well-controlled investigations" or other "valid scientific evidence" that the agency deems sufficient. 21 U.S.C. § 387j(c)(2), (4), (5).

Petitioner seeks to market [redacted] After FDA denied petitioner's marketing application, concluding that petitioner had not met this statutory standard, petitioner sought internal FDA review of the marketing denial order. That administrative review is ongoing, and a decision is expected by the end of December. To prevent "wasted judicial effort," this Court generally does not allow parties to "simultaneously seek both agency reconsideration and judicial review of an agency's order."

Wade v. FCC, 986 F.2d 1433, 1433–34 (D.C. Cir. 1993) (per curiam). The Court should require that any administrative review sought by petitioner be complete before the commencement of judicial review.

If not deemed premature, the petition should be denied on the merits. FDA reasonably concluded that, for [redacted] independent reasons, petitioner failed to satisfy its statutory burden with respect to [redacted], and that petitioner failed to satisfy its burden with respect to [redacted] for these same [redacted] reasons plus a [redacted] reason. FDA determined that petitioner failed to submit key evidence about, among other things, [redacted]. Without that information, FDA could not fully assess the risks of these products as needed to determine that their marketing would be appropriate for the protection of the public health.

There is no merit to the arguments that FDA's denial of petitioner's application violated the Tobacco Control Act, deprived petitioner of fair notice of the applicable evidentiary standard, or was otherwise arbitrary

and capricious. While FDA has broad authority to promulgate new tobacco regulations through rulemaking, that authority does not relieve FDA of its separate statutory obligation to adjudicate applications for marketing authorization and to deny any applications that fail to meet the statutory public-health standard, as FDA did here. 21 U.S.C. § 387j(c). "FDA was not required to consider alternative regulatory approaches before denying the manufacturers' applications for premarket approval." *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 26 (D.C. Cir. 2022). In addition, petitioner had ample notice of the applicable evidentiary standard, which is set forth in the statute itself, and FDA provided further notice of the evidence needed in a 2019 guidance document and in a letter to petitioner specifically identifying the deficiencies in the application. *Cf. id.* at 24 ("There was nothing new about the FDA's review of the manufacturers' applications that deprived them of fair warning.").

STATEMENT OF JURISDICTION

FDA issued an order on April 8, 2022, denying petitioner's applications to market certain new tobacco products. AR-000112–25. Petitioner filed a timely petition for review on May 6, 2022. This Court has jurisdiction under 21 U.S.C. § 387*l*(a)(1)(B).

STATEMENT OF THE ISSUES

1. Whether the petition for review of the marketing denial order is premature in light of petitioner's pending request for internal FDA review of that order.

2. Whether FDA properly denied petitioner's applications for authorization to market certain e-cigarette products because petitioner failed to submit [redacted] — and, for some products, [redacted] — key pieces of evidence about the products and thus failed to demonstrate that marketing the products would be appropriate for the protection of the public health.

STATEMENT OF THE CASE

I. Statutory Background

The Family Smoking Prevention and Tobacco Control Act established a comprehensive scheme for the regulation of tobacco products. Pub. L. No. 111-31, div. A, 123 Stat. 1776 (2009). The Act applies to products such as cigarettes and smokeless tobacco, as well as to other products made or derived from tobacco that FDA by regulation deems to be subject to the Act. 21 U.S.C. § 387a; *see also id.* § 321(rr)(1); Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. P, tit. I, subtitle B, § 111, 136 Stat. 49,

789–90 (expanding Act's definition of "tobacco product" to include products made with synthetic nicotine).

The Tobacco Control Act provision at issue here makes it unlawful for a manufacturer to introduce in interstate commerce any "new tobacco product" unless the manufacturer obtains premarket authorization from FDA. 21 U.S.C. § 387j(a)(1)–(2). The statute defines a "new tobacco product" as one that was not commercially marketed in the United States as of February 15, 2007, or that was modified after that date. *Id.* § 387j(a)(1).

The Act provides that FDA "shall deny" a manufacturer's application to market a new tobacco product "if, upon the basis of the information submitted to [FDA] as part of the application and any other information before [FDA] with respect to such tobacco product," the agency "finds that[] . . . there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2). The Act specifies that, in making that determination, FDA must evaluate "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product," taking into account both the "likelihood that existing users of tobacco products will stop using such products" and the "likelihood that those who do not

use tobacco products will start." *Id.* § 387j(c)(4). Because "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products," Tobacco Control Act § 2(4), 123 Stat. at 1777, FDA weighs (among other things) the risk that a new tobacco product will promote youth initiation and use against the product's potential for helping adults who smoke combustible cigarettes switch to a less dangerous alternative. To obtain marketing authorization, an applicant must demonstrate a net benefit to public health taking such risks and benefits into account.[1]

II. Regulatory Background

1. E-cigarettes deliver nicotine, which is "among the most addictive substances used by humans," "by vaporizing a liquid that includes other chemicals and flavorings." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). "The device heats the liquid until it generates an aerosol — or 'vapor' — that can be inhaled." *Id.*

[1] The Tobacco Control Act provides a separate premarket authorization pathway for tobacco products that are substantially equivalent to products that were commercially marketed in the United States as of February 15, 2007. 21 U.S.C. § 387j(a)(2)(A)(i)(I). That pathway is not at issue here.

In 2016, FDA exercised its statutory authority to deem e-cigarettes and other products made or derived from tobacco to be subject to the Tobacco Control Act's requirements. 81 Fed. Reg. 28,974 (May 10, 2016). Most e-cigarettes were not on the market as of February 15, 2007, and thus meet the Act's definition of a "new tobacco product" and became unlawful to market without FDA authorization after the rule's August 8, 2016 effective date. *See Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 440 (5th Cir. 2020), *cert. denied*, 141 S. Ct. 2746 (2021). As a policy matter, however, FDA decided against immediate enforcement of that statutory prohibition for products already on the market as of the rule's effective date. 81 Fed. Reg. at 28,977–78; *see id.* at 29,011 n.13.

Through enforcement policies that FDA has revised over time, the agency has sought to strike a balance between the serious risk that e-cigarettes pose to youth and their potential benefit in helping adults quit or significantly reduce smoking combustible cigarettes. FDA has "repeatedly emphasized that the availability of non-combustible options should not come at the expense of addicting a generation of children to nicotine through these same delivery vehicles." FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on*

the Market Without Premarket Authorization (Revised): Guidance for Industry 38 (Apr. 2020), https://perma.cc/V5KV-RQWN (2020 Guidance).

2. Initially, FDA announced that, for e-cigarettes already on the market as of the 2016 rule's effective date, the agency generally would not take enforcement action based on a product's lack of premarket authorization for a two- to three-year period while manufacturers prepared, and FDA reviewed, marketing applications. 81 Fed. Reg. at 28,978. In 2017 guidance, FDA extended that period until 2022. *See* 2020 Guidance 5. Before that announcement, "nationally representative data suggested that youth use of e-cigarettes had declined beginning in 2016." *Id.*

By late 2017, however, FDA began to see an alarming increase in the use of e-cigarettes by middle and high school students. 2020 Guidance 6. FDA therefore stepped up enforcement actions against products marketed to youth and against retailers that sold e-cigarettes to minors, *id.* at 6–7, and the agency sent letters directing manufacturers with significant market share to submit plans to help restrict minors' access to e-cigarettes, *id.* at 7. In response, manufacturers proposed safeguards such as age-verification technology for online sales, enhanced monitoring of retailer compliance

with age-verification and sales restrictions, contractual penalties for retailers that failed to comply with such requirements, and limits on the quantity of e-cigarettes that a customer could purchase within a particular period. *Id.*

Nonetheless, in 2019, youth e-cigarette use hit the highest levels ever recorded. 2020 Guidance 8. FDA thus revised its enforcement policy. Although FDA continued to enforce sales restrictions, it concluded that "age verification alone is not sufficient to address this issue, given the most recent data that youth use of [e-cigarette] products continues to increase." *Id.* at 44. "The reality," FDA explained, "is that youth have continued access to [e-cigarette] products in the face of legal prohibitions and even after voluntary actions by some manufacturers." *Id.* In part because many youth obtain their e-cigarettes from friends or other sources in their social networks, *id.* at 45, FDA determined that sales restrictions alone would "not be sufficient to address youth use of these products," *id.* at 44.

Accordingly, FDA's 2020 guidance outlined an enforcement policy that prioritized action against the types of products that were, at that time, especially popular among youth: flavored, cartridge-based e-cigarettes

(other than tobacco-flavored or menthol-flavored products).[2] 2020 Guidance 10. FDA emphasized the "extraordinary popularity" of flavored e-cigarettes among youth, *id.* at 13, noting that 93% of e-cigarette users aged 12–17 reported that their first e-cigarette was a flavored product, and that 71% of youth users indicated they used e-cigarettes "because they come in flavors I like," *id.* at 14. FDA also explained that the leading e-cigarette brand at that time (JUUL) was a cartridge-based product that commanded 70% of the market, and that features of cartridge-based products made them especially easy to use and conceal, and thus particularly attractive to youth. *Id.* at 15–16. FDA also made clear that it "make[s] enforcement decisions on a case-by-case basis" and that it "retains discretion to pursue enforcement action at any time against any deemed new tobacco product marketed without premarket authorization." *Id.* at 11.

Although the 2020 enforcement policy led to the removal of many flavored products from the market and was followed by a decline in youth

[2] In this brief, "flavored" e-cigarette products refer to products with flavors other than tobacco.

use, use of e-cigarettes by children and adolescents has remained at levels comparable to those that originally led FDA to declare a youth vaping epidemic. *See* AR-002936–38. After the market exit of flavored, cartridge-based e-cigarettes, there was a substantial rise in youth use of disposable e-cigarettes which had largely been excluded from the 2020 enforcement policy because, at the time that policy was developed, those products were not commonly used by youth. *See* AR-002938. As FDA recognized, "[redacted]." AR-002938.

3. Shortly before September 9, 2020, FDA received a large volume of applications to market e-cigarette products. The influx resulted in part from a court-ordered deadline in an action brought by public-health organizations. *See American Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020) (per curiam). That court observed that, "however laudable the FDA's intended regulatory response is, the record before me shows a purposeful avoidance by the industry of complying with the

premarket requirements despite entreaties from the FDA." *Id.* at 485. The court thus directed FDA to require manufacturers to submit applications for premarket authorization within 10 months of its order — a date later extended to September 9, 2020, due to the pandemic — and provided that "[p]roducts for which applications ha[d] been timely filed [could] remain on the market without being subject to FDA enforcement actions" for up to a year. *Id.* at 487.

FDA has acted on many of those applications and has granted applications for tobacco-flavored e-cigarette products when manufacturers have demonstrated that marketing the products would be appropriate for the protection of the public health. *See, e.g.*, FDA, *Technical Project Lead Review for Applications Submitted by R.J. Reynolds Vapor Company* (Oct. 12, 2021), https://perma.cc/7Z8E-FW6T.

In contrast to tobacco-flavored e-cigarettes, FDA has explained that [redacted]. *See, e.g.*, AR-000115–16, AR-002912, AR-002915, AR-002936–39. "The distinct public health hazards of flavored tobacco products, especially to young people, are extensively documented."

Prohibition Juice Co. v. FDA, 45 F.4th 8, 19 (D.C. Cir. 2022). Thus, for FDA to find that the marketing of such products is appropriate for the protection of the public health, applications to market flavored products face a greater burden to show that this significant risk to youth is outweighed by likely benefits to existing users of tobacco products "[redacted]" to "[redacted]." AR-002912. "[redacted]" to support the finding of a net positive effect. AR-002936; *see* AR-002912, AR-002940 n.18; *see also Prohibition Juice*, 45 F.4th at 19–20. Some manufacturers submitted evidence of a type that could potentially support such a finding for their flavored products, and those applications remain under agency review. *See, e.g.*, Motion for Voluntary Dismissal, *Turning Point Brands, Inc. v. FDA*, No. 21-3855 (6th Cir. Oct. 8, 2021), Dkt. No. 19 (noting FDA's agreement to reconsider applications when it overlooked such evidence). FDA has denied applications to market e-cigarette products where manufacturers failed to submit evidence that satisfies the statutorily required showing.

III. FDA's Denial of Petitioner's Applications to Market E-Cigarette Products

Petitioner applied to market [redacted] e-cigarette products in April 2020. AR-002916. These products include [redacted]. AR-002916. Each of these products is a new tobacco product within the meaning of the Tobacco Control Act and thus subject to the Act's premarket authorization requirement.

After sending petitioner a letter identifying the specific evidentiary deficiencies in its application and providing an opportunity to cure those deficiencies,[3] AR-000095–111, FDA weighed the evidence regarding the potential "risks and benefits to the population as a whole," 21 U.S.C.

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[3] FDA has no longstanding policy of issuing more than one deficiency letter. While the agency had "on average issue[d] two deficiency letters" early in the premarket review process when the agency had less experience with tobacco applications, 86 Fed. Reg. 55,300, 55,403 (Oct. 5, 2021), FDA has denied applications from hundreds of other manufacturers without issuing a deficiency letter. The deficiency letter here notified petitioner that FDA "[redacted]" petitioner's application. AR-000095. Petitioner also had the same opportunity as prior applicants to submit an unlimited number of amendments to remedy deficiencies in its application. *Cf.* 21 C.F.R. § 1114.9(a) (final rule confirming FDA's practice of allowing manufacturers to amend applications, with no limit on the number of amendments permitted). Petitioner elected to submit an amendment here. *See* AR-000125, Response to Deficiency Letter.

§ 387j(c)(4), and concluded that petitioner had not met its burden of demonstrating that the marketing of its products was appropriate for the protection of the public health, AR-000112–25. FDA's conclusion with respect to petitioner's [redacted] was based on [redacted] independent grounds. AR-000113–17, AR-002913–16, AR-002951–54. FDA's conclusion with respect to petitioner's [redacted] was based on these same [redacted] grounds plus [redacted] ground. AR-000113–17, AR-002913–16, AR-002951–54.

A. Lack of [redacted]

[redacted] FDA found that [redacted]. AR-000113–14, AR-002913–14, AR-002919, AR-002954–55. As FDA explained, evidence shows that [redacted].[4] AR-000113,

[4] A "harmful and potentially harmful constituent" is "any chemical or chemical compound in a tobacco product or in tobacco smoke that: (a) is,

AR-002914, AR-002954. FDA explained that [redacted]. AR-000113, AR-002954. FDA concluded that, "[redacted]." AR-002951–52; *see also* AR-002914, AR-002925.

B. Lack of information about [redacted]

[redacted] FDA found that petitioner's application lacked key information about [redacted]. AR-000114, AR-002914, AR-002924–25, AR-002952. FDA explained that petitioner had not [redacted]

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or potentially is, inhaled, ingested, or absorbed into the body, including as an aerosol (vapor) or any other emission; and (b) causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products." FDA, "*Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and FDA Staff (Revised)* 2 (Aug. 2016), https://perma.cc/HA3H-QXVQ.

[redacted]. AR-000114, AR-002952. As FDA explained, evidence shows that [redacted]. AR-000114, AR-002924–25. FDA also explained that petitioner had not [redacted]. AR-000114, AR-002924, AR-002952. As FDA explained, evidence shows that [redacted]. AR-000114, AR-002924, AR-002952. FDA concluded that, "[redacted]." AR-002952; *see also* AR-002914, AR-002925.

C. Lack of information about [redacted]

[redacted] FDA found that petitioner's application lacked important information about [redacted]. AR-000114, AR-002914, AR-002920, AR-002926, AR-002952. This information includes [redacted]

[redacted]. AR-000114, AR-002920. As FDA explained, this information is necessary to [redacted]. AR-002952. FDA concluded that, "[redacted]" AR-002952; *see also* AR-002914.

D. Lack of adequate [redacted]

[redacted] FDA found that petitioner's application lacked [redacted]. AR-000115, AR-002914, AR-002922, AR-002926, AR-002952. As FDA explained, evidence shows that [redacted]. AR-000115, AR-002926. [redacted]

[redacted]. AR-000115, AR-002914, AR-002922, AR-002952. FDA also explained that [redacted]. AR-000115, AR-002922, AR-002926. FDA concluded that, "[redacted]." AR-002952; *see also* AR-002914, AR-002922, AR-002926.

E. Lack of adequate information in [redacted]

[redacted] FDA found that [redacted].[5] AR-000116–17, AR-002916, AR-002919–21, AR-002923, AR-002925, AR-002953. This information included

[5] Master files allow an applicant to rely on trade secrets or confidential commercial information from another party, like a supplier, to support an application without seeing the information. For background on master files, see FDA, *Submit and Reference Tobacco Product Master Files* (June 2020), https://perma.cc/F357-TT25.

[redacted]. AR-00116, AR-002919, AR-002921, AR-002925. FDA concluded that, "[redacted]." AR-002953; *see also* AR-002916, AR-002925.

F. Lack of evidence that [redacted]

In addition to these [redacted] grounds on which FDA denied petitioner's application to market all of petitioner's e-cigarette products, FDA's denial of petitioner's application to market [redacted] was also based on a [redacted] ground. AR-000115–16, AR-002915–16, AR-002932, AR-002935–43, AR-002952–53, AR-002957–58.

FDA determined that [redacted]. AR-000115–16, AR-002915, AR-002932, AR-002936–39, AR-002952, AR-002957. FDA also reiterated its determination from the 2020 guidance that "[redacted]

[redacted]

[redacted]

[redacted]" meet the statutory standard. AR-000116 n.3, AR-002915 n.6, AR-002942, AR-002953 n.21, AR-002957 n.23.

FDA then considered whether [redacted]

[redacted]

[redacted]

[redacted]. AR-000116, AR-002915, AR-002939–41, AR-002953, AR-002957. In particular, the agency [redacted]

[redacted]

[redacted]

[redacted]. AR-000116, AR-002915, AR-002932, AR-002939–41, AR-002952–53, AR-002957; *see Prohibition Juice*, 45 F.4th at 19 (approving FDA's determination, in the context of another marketing denial order, that "if [a] new product carried greater risks but no overmatching greater benefits" compared to another product, then "authorizing [the new product] would not on balance serve public health").

In its application to market [redacted], petitioner relied on [redacted]. Br. 47–48; *see also* AR-002931. Petitioner also relied on [redacted]. Deficiency Resp. 19, at 2, 6. In addition, petitioner cited [redacted]. AR-000116, AR-002932.

FDA concluded that [redacted]. AR-000116, AR-002915, AR-002931–32, AR-002941. FDA determined that [redacted]

[redacted]. AR-000116, AR-002915, AR-002931, AR-002941. FDA also determined that [redacted] ." AR-002915; *see also* AR-002931.

FDA determined that [redacted] was not sufficient to show that [redacted]. FDA determined that [redacted] ." AR-002941; *see Prohibition Juice*, 45 F.4th at 21–22 (noting FDA's findings about cross-sectional surveys and their inability to reliably assess behavior change over time). FDA also determined that petitioner "[redacted], AR-002931, and that, in any event, [redacted]," AR-002931.

While petitioner cited [redacted]. AR-002931–32. Based on this review, FDA concluded that "[redacted]." AR-000116.

FDA concluded that, "[redacted]." AR-002916; *see also* AR-002953.

IV. Petitioner's Administrative Appeal of the Marketing Denial Order

After filing this petition for review of the marketing denial order, petitioner submitted a request for FDA supervisory review of the marketing denial order on June 6, 2022. *See* 21 C.F.R. § 10.75. FDA accepted petitioner's request for supervisory review, which remains pending before

the agency. FDA expects to resolve the request for supervisory review by December 31, 2022.

V. This Court's Denial of Petitioner's Emergency Stay Motion

Petitioner sought an emergency stay of the marketing denial order from this Court. A motions panel denied the stay, concluding that petitioner had not "made a strong showing that it is likely to succeed on the merits." *Fontem US, LLC v. FDA*, No. 22-1076, 2022 WL 2761393, at *1 (D.C. Cir. July 12, 2022) (per curiam). Citing "record evidence indicating that [FDA] likely found each of the grounds for the marketing denial order independently sufficient to support its decision," the motions panel explained that it could "sustain the decision as long as one is valid and the agency would clearly have acted on that ground even if the other[s] were unavailable." *Id.* (second brackets in original) (quoting *Casino Airlines, Inc. v. National Transp. Safety Bd.*, 439 F.3d 715, 717 (D.C. Cir. 2006)). The motions panel determined that FDA had "likely afforded [petitioner] fair notice" "[a]s to multiple bases for the marketing denial order." *Id.*

SUMMARY OF ARGUMENT

I. Petitioner's pending request for FDA supervisory review of the marketing denial order renders this petition for judicial review of that same

order premature. "If a party determines to seek reconsideration of an agency ruling," this Court has held that "it is a pointless waste of judicial energy for the court to process any petition for review before the agency has acted on the request for reconsideration." *TeleSTAR, Inc. v. FCC*, 888 F.2d 132, 134 (D.C. Cir. 1989) (per curiam). The Court should therefore require that the administrative review sought by petitioner be complete before the commencement of judicial review.

II. If the petition is not deemed premature, it should be denied on the merits. Notwithstanding FDA's 2019 guidance about the contents of tobacco marketing applications and FDA's letter notifying petitioner of the specific evidentiary deficiencies in its application, petitioner failed to provide important information about [redacted]. This information included: [redacted]

[redacted]. FDA reasonably determined that, without each of these pieces of evidence, the agency could not find that allowing petitioner to market its e-cigarette products would be appropriate for the protection of the public health.

Contrary to petitioner's contention, FDA's conclusion in this respect does not implicate the Tobacco Control Act's provisions governing the promulgation of "tobacco product standards" or manufacturing requirements. Nothing in those separate provisions relieves FDA of the responsibility to consider the risks of tobacco products when reviewing a manufacturer's application to market a new tobacco product pursuant to § 387j(c). Nor was there any unfair surprise about the evidentiary standard that, when unmet, led FDA to deny petitioner's application. Petitioner had ample notice of the standard from FDA's letter to petitioner identifying the specific deficiencies in the application, the 2019 guidance document, and the statute itself.

III. Even if there were an error in any of the grounds on which FDA denied petitioner's application, the error would be harmless. Each of the [redacted] — or, for petitioner's [redacted], [redacted] — grounds was an

independently sufficient reason for the denial as to those products, as the motions panel correctly concluded in denying the emergency stay motion. *Fontem US, LLC v. FDA*, No. 22-1076, 2022 WL 2761393, at *1 (D.C. Cir. July 12, 2022) (per curiam). Thus, absent a showing that all of FDA's grounds for denying authorization for a particular product were unlawful, any error was harmless.

STANDARD OF REVIEW

FDA's denial of an application to market a new tobacco product is reviewed under the familiar, deferential standards established by the Administrative Procedure Act and may be held unlawful and set aside only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2); *see* 21 U.S.C. § 387*l*(b) (incorporating this standard). Review under that standard "is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

ARGUMENT

I. Petitioner's Pending Administrative Appeal Renders This Petition Premature

Petitioner has filed a request for FDA supervisory review of the marketing denial order, *see* 21 C.F.R. § 10.75, and has raised many of the same arguments it raises here. FDA has accepted the request for supervisory review, which is ongoing, and expects to resolve the supervisory review request by December 31, 2022.[6] To conserve judicial resources, this Court should require that the administrative review sought by petitioner be complete before the commencement of judicial review.

"It is well established that a party may not simultaneously seek both agency reconsideration and judicial review of an agency's order[] . . . ." *Wade v. FCC*, 986 F.2d 1433, 1433 (D.C. Cir. 1993) (per curiam). A "pending petition for administrative reconsideration renders the underlying agency action nonfinal, and hence unreviewable." *TeleSTAR, Inc. v. FCC*, 888 F.2d 132, 133 (D.C. Cir. 1989) (per curiam) (quoting *United Transp. Union v. Interstate Commerce Comm'n*, 871 F.2d 1114, 1114 (D.C. Cir. 1989)). The aim

[6] A decision on a request for supervisory review under 21 C.F.R. § 10.75 may be appealed to the FDA Commissioner.

of this rule is to prevent "wasted judicial effort," *Wade*, 986 F.2d at 1434, given the "possibility that the order complained of will be modified in a way which renders judicial review unnecessary," *Stone v. Immigration & Naturalization Serv.*, 514 U.S. 386, 392 (1995) (quoting *Outland v. Civil Aeronautics Bd.*, 284 F.2d 224, 227 (D.C. Cir. 1960)); *accord Friends of Earth v. U.S. Nuclear Regulatory Comm'n*, 851 F. App'x 212, 214 (D.C. Cir. 2021) (per curiam). Here, for example, given the significant overlap between the arguments that petitioner makes here and those made in its request for further administrative review, the outcome of that administrative review could potentially change the legal issues presented to the Court, either by obviating the need for their consideration or altering their contours. Judicial review of the agency's decision before that further administrative determination would be inefficient. Because this risk of wasted judicial effort "arises whether a party seeks agency reconsideration before, simultaneous with, or after filing an appeal or petition for judicial review," the Court applies the rule "regardless of the order of filing." *Wade*, 986 F.2d at 1434.

To "discourage the filing of petitions for review until after the agency completes the reconsideration process," this Court employs a "bright line

test" under which such petitions are treated as "incurably premature" even if there is "subsequent action by the agency on a motion for reconsideration" while the petition is pending. *TeleSTAR*, 888 F.2d at 134. Review by the Court is then proper, if timely sought, once the administrative process concludes and the order becomes final. *Id.*

If the Court were to reach the merits, however, the petition for review should be denied for the reasons set out below.

II. FDA Reasonably Concluded That Petitioner Failed to Show That Marketing Its E-Cigarette Products Would Be Appropriate for the Protection of the Public Health

For [redacted] — and, for petitioner's [redacted], [redacted] — independent reasons, FDA reasonably concluded that petitioner failed to show that marketing its e-cigarette products would be appropriate for the protection of the public health. There is no merit to petitioner's contentions that FDA denied petitioner fair notice, violated the statute, acted arbitrarily and capriciously, or erred prejudicially.

A. FDA reasonably determined that [redacted]

[redacted] FDA explained that [redacted].

AR-000113, AR-002954. As FDA explained, evidence shows that [redacted]. AR-000113, AR-002914, AR-002954.

Petitioner focuses on its products' [redacted] — and contends that no [redacted] is required by statute or regulation. Br. 31–32. Contrary to petitioner's contention, however, FDA's determination was based not on [redacted], but instead on the lack of evidence of [redacted].[7] AR-002951–52. Without such evidence, FDA could not fully assess the risks presented by these products and could not

[7] While petitioner contends that FDA's request for [redacted] was "nonsensical[]" because petitioner's e-cigarette products [redacted], Br. 31–32, [redacted] in fact underscores the need for [redacted]. With no [redacted], it was even more important for petitioner to show that its e-cigarette products [redacted]. AR-002925.

conclude that the risks were sufficiently low as to make their marketing appropriate for the protection of the public health.

For the same reason, petitioner is wrong to assert that FDA treated its e-cigarette products differently than a competitor's product that [redacted] yet received marketing authorization. Br. 33–34. Unlike the competitor's product, petitioner's products [redacted], and petitioner did not [redacted]. AR-002924–25. While petitioner speculates that the competitor [redacted], petitioner provides no factual basis for that speculation. Br. 33. The competitor's application was not part of "the full administrative record that was before the [agency] at the time [it] made [its] decision" on petitioner's application, and thus it is not properly considered here.[8] *See Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402,

[8] Petitioner has raised this differential treatment argument in its pending request for internal FDA review. FDA's determination of that request may sharpen the record for judicial review on this issue, which further shows why this Court should require that the administrative

420 (1971). Regardless, while FDA cannot discuss here the specifics of the competitor's application, which is confidential, there is no substance to petitioner's speculation, and FDA will make the competitor's materials available to the Court in camera if the Court so requests.

Petitioner ultimately acknowledges that — unlike the competitor — [redacted] but contends that FDA never requested [redacted]. Br. 31–32. Contrary to petitioner's contention, FDA's deficiency letter asked petitioner to [redacted]. AR-000096, AR-000101–02. FDA's 2019 guidance also indicated that [redacted]." FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery*

review sought by petitioner be complete before the commencement of judicial review. *See supra* Section I.

Systems: Guidance for Industry [redacted] (June 2019), https://perma.cc/YTD3-DF3Z (2019 Guidance) (announced at 84 Fed. Reg. 27,200 (June 12, 2019)); *see also Howmet Corp. v. EPA*, 614 F.3d 544, 554 (D.C. Cir. 2010) (explaining that published agency guidance can provide fair notice). That [redacted] would naturally include [redacted].

In addition to FDA's deficiency letter and 2019 guidance, the Tobacco Control Act itself gave petitioner notice of the evidentiary burden that applicants must carry. "It was Congress, not the FDA, that imposed . . . on new tobacco products, including e-cigarettes," the "requirement that each new tobacco product's risks not outweigh its benefits to the public health." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 281 (D.C. Cir. 2019). The Tobacco Control Act itself requires FDA to deny an application unless the manufacturer demonstrates that marketing its new product is "appropriate for the protection of the public health," considering "the risks and benefits to the population as a whole." 21 U.S.C. § 387j(c)(2), (4). And the Act directs FDA to make that finding, "when appropriate," based on "well-controlled investigations" or other "valid scientific evidence" that the agency deems sufficient. *Id.* § 387j(c)(5).

In arguing that FDA failed to provide fair notice, petitioner relies on inapposite case law (Br. 28–29), in which an agency took action contrary to a longstanding interpretation without giving the regulated party an opportunity to comply with the new interpretation. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155–58 (2012) (agency interpreted ambiguous regulations to impose "potentially massive liability" for a "longstanding" practice that agency had never suggested was unlawful and that occurred well before interpretation was announced); *Salzer v. FCC*, 778 F.2d 869, 875 (D.C. Cir. 1985) (agency dismissed application without consideration of merits based on interpretation of a rule that was contrary to both the rule's "clearly reasonable interpretation" and the agency's prior "mandate"). Here, as explained above, FDA's denial of petitioner's application was consistent with its 2019 guidance, its deficiency letter to petitioner, and the statute itself. *Cf. Prohibition Juice Co. v. FDA*, 45 F.4th 8, 21, 24 (D.C. Cir. 2022) (finding that the "2019 Guidance gave fair notice of the analysis the agency would perform" and that "FDA's final determinations were consistent with the 2019 Guidance, undercutting [the manufacturers' notice] claim").

Finally, petitioner asserts that [redacted] should have been sufficient because the data was generated under conditions that went beyond how petitioner expects consumers to use its e-cigarette products. Br. 31. But this assertion is based on [redacted], *id.* (quoting Deficiency Resp. 2, at 2), not the "[redacted]" that FDA requested when giving petitioner an opportunity to cure the deficiency, AR-000096, AR-000101–02, and FDA reasonably determined that petitioner's evidence was insufficient to make the statutorily required showing. That determination, based on FDA's "evaluation[] of scientific data within its area of expertise," "is entitled to a 'high level of deference,'" *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998) (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995)), and petitioner has offered no basis to overcome that deference.

B. FDA reasonably determined that [redacted]

[redacted] FDA explained that petitioner's application [redacted]

[redacted]. AR-000114, AR-002914, AR-002924–25, AR-002952. The missing information included [redacted]. AR-000114, AR-002952, AR-002924–25. The missing information also included [redacted]. AR-000114, AR-002924, AR-002952.

Petitioner does not dispute that [redacted] but contends that FDA did not request this information. Br. 37–38. Contrary to petitioner's contention, FDA's deficiency letter asked petitioner to "[redacted]," including "[redacted]" and

"[redacted]," "[redacted]."[9] AR-000096. This data was necessary, the deficiency letter explained, to "[redacted]" and thus whether their marketing would be appropriate for the protection of the public health. AR-000096.

Petitioner is similarly wrong to assert that it lacked notice of the need for [redacted]. Br. 34–36. FDA's deficiency letter asked petitioner to "[redacted]." AR-000096. That request comports with FDA's statement in its 2019 guidance that [redacted]." 2019 Guidance [redacted]; *see also*

[9] Petitioner's contention (Br. 37) that the deficiency letter requested [redacted] — not [redacted] — overlooks the letter's separate request for "[redacted]" "[redacted]." AR-000096.

id. at [redacted] (advising that [redacted]").[10] When petitioner failed to provide the required information concerning [redacted], FDA reasonably concluded that petitioner had not provided full information regarding the products' risks and therefore had not carried its burden of satisfying the statutory public-health standard.

C. FDA reasonably determined that [redacted]

[redacted] FDA explained that petitioner's application [redacted].

[10] There is no merit to petitioner's suggestion that [redacted] should have been unnecessary because the [redacted]. Br. 34–35. The shortcoming identified by FDA was not [redacted], but [redacted]. AR-000114, AR-002924, AR-002952.

AR-000114, AR-002914, AR-002920, AR-002926, AR-002952. As FDA explained, this rudimentary information is necessary to [redacted]. AR-002952.

Petitioner does not dispute that [redacted] but asserts that FDA did not request the information. Br. 40–41. The requirement to submit this information, however, comes from the Tobacco Control Act itself, which states that [redacted]." 21 U.S.C. § 387[redacted]. FDA also advised petitioner of the need to submit much of this information in the deficiency letter and the agency's 2019 guidance. AR-000099 (requesting [redacted]); 2019 Guidance [redacted] (recommending that applications include "[redacted]"). Despite having ample notice, petitioner failed to provide the required information,

and FDA reasonably concluded that petitioner had failed to satisfy the statutory public-health standard.

Notwithstanding petitioner's assertion, Br. 41–42, this conclusion is not contradicted by FDA's statements about one of petitioner's suppliers, [redacted]. The fact that petitioner provided some information about the supplier that did not raise significant concerns says nothing about other information that petitioner admittedly failed to provide.

Petitioner is also wrong to contend that FDA could not consider [redacted] in reviewing a marketing application without first adopting a new manufacturing requirement or a tobacco product standard through notice-and-comment rulemaking. Br. 22–27, 28, 32, 38–40, 42–43. While Congress gave FDA broad authority to promulgate new manufacturing requirements and tobacco product standards through rulemaking, 21 U.S.C. §§ 387f(e), 387g, it also expressly directed FDA to adjudicate applications for marketing authorization under § 387j and to deny any applications that are deficient in any of four enumerated respects. *Id.* § 387j(c). Congress further specified that, in adjudicating marketing applications, FDA is to consider a panoply of information about product safety and manufacturing, including

"full reports of all information[] . . . concerning investigations which have been made to show the health risks of [the new] tobacco product," *id.* § 387j(b)(1)(A); "a full description of the methods used in, and the facilities and controls used for, the manufacture[] . . . of" the product, *id.* § 387j(b)(1)(C); and "such other information relevant to the subject matter of the application as [FDA] may require," *id.* § 387j(b)(1)(G).

The authority to adjudicate marketing applications and the authority to promulgate new manufacturing requirements and tobacco product standards through rulemaking are distinct sources of authority. And the provisions governing marketing applications expressly put the onus on manufacturers, not FDA, to establish the appropriateness of new products before marketing — a burden that petitioner is trying to flip here by invoking inapposite provisions. As directed by Congress, FDA considered the methods, facilities, and controls associated with petitioner's manufacturing process. That information is relevant to assessing both the adequacy of those processes and a product's appropriateness for the protection of public health. Petitioner failed to carry its burden of demonstrating that these statutory standards were met, even after receiving a deficiency letter outlining these issues. Petitioner's attempt to

now claim that the shortcoming here was on the part of the agency runs counter to the terms of the statute. Petitioner failed to adduce the evidence required by Congress. And "FDA was not required to consider alternative regulatory approaches before denying the manufacturers' applications for premarket approval." *Prohibition Juice*, 45 F.4th at 26.

Petitioner asserts that FDA failed to consider manufacturing requirements and tobacco product standards separately from the public-health standard and thus did not apply the correct statutory framework. Br. 21, 28. Contrary to petitioner's assertion, in adjudicating petitioner's application, FDA separately addressed each of the four statutory requirements that applications must satisfy, including the public-health standard, manufacturing practices, labeling, and tobacco product standards. 21 U.S.C. § 387j(c)(2); AR-002950–51.

D. FDA reasonably determined that [redacted]

[redacted] FDA explained that petitioner's application [redacted]

[redacted]. AR-000115, AR-002914, AR-002922, AR-002926, AR-002952. As FDA explained, evidence shows that

[redacted]. AR-000115, AR-002926. [redacted]. AR-000115, AR-002914, AR-002922, AR-002952. FDA also explained that [redacted]. AR-000115, AR-002922, AR-002926.

Petitioner does not dispute that [redacted]. Br. 42–47. Instead, petitioner asserts that FDA had indicated that [redacted]. Br. 43–44. What the deficiency letter said, however, was that "[redacted]

[redacted]." AR-000104 (emphases added). This request in the deficiency letter mirrored FDA's 2019 guidance, which advised that "[redacted]." 2019 Guidance [redacted]. Petitioner failed to provide the [redacted] evidence that FDA requested, and FDA reasonably concluded that, in the absence of such evidence, petitioner had not satisfied the statutory public-health standard.

Petitioner contends that FDA's request for [redacted] evidence should have been satisfied by petitioner's claim that [redacted]." Br. 44 (quoting Deficiency Resp. 13, at 13). But FDA reasonably explained that, notwithstanding petitioner's claim, the "[redacted]." AR-002926. Petitioner submitted no evidence to dispel this

concern and has offered no basis to overcome the considerable deference given to FDA's evaluation of evidence within its area of expertise. *See Serono Labs.*, 158 F.3d at 1320.

As explained above, *supra* pp. 42–44, there is no merit to petitioner's contention that FDA could not consider the failure to provide this type of key information in reviewing a marketing application without first adopting a new manufacturing requirement or tobacco product standard through notice-and-comment rulemaking. FDA explained how [redacted] affects specific public health risks, which FDA is statutorily required to consider when adjudicating marketing applications under the public-health standard. AR-002922 ("[redacted]."); 21 U.S.C. § 387j(c)(4). Indeed, petitioner apparently recognized the relevance of this information when petitioner attempted to provide it and thereby satisfy the statutory public-health standard in response to FDA's deficiency letter. Petitioner's response purportedly provided "[redacted]

[redacted]," asserted that "[redacted]," and concluded that [redacted]." Deficiency Resp. 13, at 11, 13. Petitioner essentially recognized the propriety of FDA's consideration of this information when deciding whether an application meets the statutory public-health standard but fell short in producing the evidence to satisfy that standard.

Petitioner also acknowledges that [redacted]. Br. 46–47. Petitioner asserts, however, that FDA did not request this [redacted]. *Id.* Contrary to petitioner's assertion, FDA's deficiency letter asked for "[redacted]." AR-000104. The need for this information is also apparent from the Tobacco Control Act itself, which says that FDA's determination of whether a tobacco product is appropriate for the protection of the public health "shall[] . . . be determined on the

basis of well-controlled investigations" or other "valid scientific evidence." 21 U.S.C. § 387j(c)(5)(A)–(B). FDA's 2019 guidance advised that [redacted]. 2019 Guidance [redacted]. When petitioner failed to provide this required [redacted], FDA reasonably concluded that petitioner had not satisfied the statutory public-health standard.

E. FDA reasonably determined that [redacted]

[redacted] FDA explained that petitioner's application relied on [redacted]. AR-000116–17, AR-002916, AR-002919–21, AR-002923, AR-002925, AR-002953. This information included [redacted]. AR-00116, AR-002919, AR-002921, AR-002925.

Petitioner does not dispute that [redacted] were deficient or that those deficiencies were a proper basis for FDA's denial of its application. Br. 52–54. Instead, petitioner asserts that FDA did not provide adequate notice of the deficiencies [redacted]. Br. 53–54.

Contrary to petitioner's assertion, FDA's November 2020 deficiency letter notified petitioner that the agency had "[redacted]." AR-000107. The letter explained that [redacted] advised petitioner to [redacted], and informed petitioner that [redacted]. AR-000107.

In a simultaneous deficiency letter to [redacted], FDA requested [redacted]

[redacted]. AR-014716-A–17-A. When this information was not provided, FDA reasonably concluded that [redacted] remained deficient because it lacked key information about [redacted]." AR-014721-A.

The issues with [redacted] were not included in FDA's deficiency letter to petitioner because [redacted]. Deficiency Resp. 13, at 15. Because petitioner's original application did not mention [redacted], FDA initially had no reason to [redacted] and no reason to include the deficiencies [redacted] in the deficiency letter to petitioner. *See* FDA, *Tobacco Product Master Files: Guidance for Industry* [redacted]

(May 2016), https://perma.cc/Z7DC-VPBB (announced at 81 Fed. Reg. 28,778 (May 10, 2016)) ("[redacted].").

Without the required information [redacted], FDA reasonably concluded that petitioner had not carried its burden of satisfying the statutory public-health standard.

F. FDA reasonably determined that [redacted]

FDA began its analysis of petitioner's application to market [redacted] by considering the risks of [redacted]. FDA reasonably determined that [redacted]

[redacted]. AR-000115–16, AR-002915, AR-002932, AR-002936–39, AR-002952, AR-002957; *see Prohibition Juice*, 45 F.4th at [redacted] (noting that "[redacted]"). FDA also reasonably determined, based on its extensive experience, that [redacted]. AR-000116 n.3, AR-002915 n.6, AR-002942, AR-002953 n.21, AR-002957 n.23.

FDA then explained that "[redacted]." AR-002936; *see also* AR-002940 n.18, AR-002912. Thus, [redacted]. AR-000116, AR-002912. In light of the lower risk [redacted], *see* FDA, *Premarket Tobacco Product Marketing Granted Orders* (June 10, 2022), https://perma.cc/FNU4-J2NJ, FDA looked for evidence that [redacted]

[redacted], AR-002912–13, AR-002915. This Court has held that [redacted] [redacted] [redacted]." *Prohibition Juice*, 45 F.4th at [redacted].

FDA determined that [redacted] [redacted] [redacted] [redacted]. FDA determined that [redacted] [redacted] [redacted] [redacted] [redacted]. AR-002915, AR-002931. If anything, FDA explained, this evidence showed that [redacted] [redacted] [redacted] [redacted]. AR-000116, AR-002915, AR-002931, AR-002941. And while petitioner cited [redacted] [redacted]

[redacted]." AR-000116.

Petitioner does not dispute [redacted].[11] Br. 47–52. Petitioner also acknowledges that [redacted]. Br. 49 n.17. And petitioner does not dispute [redacted]. Br. 47–52.

Instead, petitioner asserts that FDA changed the relevant standard during the adjudication process by requiring that "[redacted]." Br. 49 (emphasis omitted).

[11] Petitioner asserts that FDA "[redacted]," Br. 48 (brackets in original) (quoting AR-002832), but omits the second part of the explanation in the same paragraph that "[redacted]" AR-002832. FDA ultimately determined that "[redacted]." AR-002882.

Contrary to petitioner's assertion, FDA applied the same [redacted] standard throughout the process. The Tobacco Control Act provides that FDA's public-health finding "shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." 21 U.S.C. § 387j(c)(4). [redacted] and "[redacted]. *Prohibition Juice*, 45 F.4th at [redacted]. When petitioner's application did not include adequate evidence in this regard, FDA's deficiency letter requested evidence "[redacted]." AR-000107. And when petitioner did not submit this evidence in response to the deficiency letter, FDA reasonably determined that "[redacted]

[redacted]." AR-000116. As this Court has held, this kind of [redacted]." *Prohibition Juice*, 45 F.4th at [redacted].

Petitioner is wrong to assert that a footnote in the denial order announced a new standard. Br. 48–49. There, FDA explained that "[redacted]" meet the statutory standard. AR-000116 n.3. That statement is a straightforward application of the principle that "[redacted]," AR-002936, which this Court has held "[redacted]," *Prohibition Juice*, 45 F.4th at [redacted]. Contrary to petitioner's assertion, Br. 50, FDA has not suggested that [redacted] are necessary. But because [redacted]

[redacted]. AR-000116, AR-002912.

Nor is there merit to petitioner's contention that this standard is "lacking in definition." Br. 50–51. The standard is set forth by statute, which requires FDA to evaluate whether marketing the new product is "appropriate for the protection of the public health," taking into account the "likelihood that existing users of tobacco products will stop using such products" and the "likelihood that those who do not use tobacco products will start." 21 U.S.C. § 387j(c)(2), (4). FDA applies this standard in a straightforward way by "[redacted]." *Prohibition Juice*, 45 F.4th at [redacted].

Petitioner suggests that this standard is unachievable because no [redacted] have been authorized to date. Br. 51–52. But many marketing applications for [redacted] remain pending, and FDA continues to evaluate in each instance whether there is evidence demonstrating that [redacted] provides a net benefit to the public

health notwithstanding [redacted] — consistent with § 387j(c).

III. FDA's [redacted] Grounds for Denying Petitioner's Application Were Independent, and Thus Any Error in Any One Ground Was Harmless

Even assuming there were merit to petitioner's challenge to any one of FDA's [redacted] independent grounds for denying its application, any such error is harmless. The Tobacco Control Act makes marketing orders subject to review "in accordance with chapter 7 of Title 5," 21 U.S.C. § 387*l*(b), thus incorporating the Administrative Procedure Act's rule of harmless error, *see* 5 U.S.C. § 706 (instructing that "due account shall be taken of the rule of prejudicial error" in conducting arbitrary-and-capricious review).

Because each of the grounds on which petitioner's application was denied was an independently sufficient reason for the denial as to those products, as the motions panel correctly concluded in denying the emergency stay motion, *see Fontem US, LLC v. FDA*, No. 22-1076, 2022 WL 2761393, at *1 (D.C. Cir. July 12, 2022) (per curiam), petitioner fails to demonstrate that any harm flowed from any error in less than all of these grounds. *See Steel Mfrs. Ass'n v. EPA*, 27 F.3d 642, 649 (D.C. Cir. 1994) (per

curiam) (finding error harmless because agency had "adequate and independent grounds for" its decision); *see also Prohibition Juice*, 45 F.4th at 19 (explaining that "the 'burden of showing that an error is harmful normally falls upon the party attacking the agency's determination'" and declining to set aside a marketing denial order where the petitioners had failed to show that a purported error was prejudicial (quoting *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009))).

In asserting that the grounds were not independent bases for the denial, Br. 55–58, petitioner does not address or even acknowledge the motions panel's conclusion that the "record evidence indicat[es] that [FDA] likely found each of the grounds for the marketing denial order independently sufficient to support its decision," *Fontem*, 2022 WL 2761393, at *1. Petitioner's assertion is also at odds with FDA's explanation of its decision. FDA identified each separate evidentiary shortcoming in petitioner's application and explained that "[redacted]" the requested evidence on that particular issue, "[redacted]."[12] AR-002952–53;

[12] Indeed, for one ground — [redacted] — FDA explained that petitioner's failure to submit a subset of the

accord AR-002914, AR-002916, AR-002922, AR-002925, AR-002926. This conclusion is further supported by the denial order's explanation that each separate piece of evidence that petitioner had failed to provide "[redacted] — not that petitioner could make a stronger showing on other issues to compensate for these deficiencies. AR-000113–16.

Notwithstanding these explanations in the record, petitioner contends that each of the grounds identified in the denial order was not independently sufficient because the ultimate statutory standard is a balancing test. Br. 56–57. But here, FDA explicitly stated that each deficiency, standing alone, prevented the agency from finding that petitioner had satisfied the ultimate statutory standard — not that the

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required evidence ([redacted] was an independently sufficient reason for FDA's denial of petitioner's application. AR-002922 ("[redacted]"). Thus, any error in the other deficiency concerning [redacted] identified by FDA — [redacted] — was also harmless. *See supra* Section II.D.

deficiencies, considered together, outweighed the other information provided by petitioner. AR-002914, AR-002916, AR-002922, AR-002925, AR-002926, AR-002952–53.

While petitioner emphasizes the denial order's use of "[redacted]" to introduce the [redacted] numbered paragraphs listing the grounds for the denial, Br. 57 (emphasis omitted) (quoting AR-000113), that word denotes only [redacted], without indicating whether any aspects of that reasoning are independently sufficient grounds for the decision. Here, the record evidence discussed above demonstrates that FDA treated each ground as an independently sufficient reason for the denial of petitioner's application. Thus, absent a showing that all of FDA's grounds for denying authorization for a particular product were unlawful, any error was harmless.

CONCLUSION

For the foregoing reasons, the petition for review should be dismissed as premature or, in the alternative, denied.

Respectfully submitted,

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October 2022

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULES OF APPELLATE PROCEDURE 27(D) AND 32(A)

I certify that this brief complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 27(d)(1)(E), 32(a)(5), and 32(a)(6) because it has been prepared in 14-point Book Antiqua, a proportionally spaced typeface, using Microsoft Word.

I further certify that this brief complies with the type-volume limitation of Rule 27(d)(2)(A) because it contains 11,841 words, excluding the parts of the document exempted under Rule 32(f), according to the count of Microsoft Word.

October 6, 2022

s/ *Garrett Coyle*
GARRETT COYLE

CERTIFICATE OF SERVICE

I certify that on October 7, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ *Garrett Coyle*
GARRETT COYLE

ADDENDUM

TABLE OF CONTENTS

5 U.S.C. § 706 – Scope of review.

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

21 U.S.C. § 321 – Definitions; generally.

* * *

(rr)(1) The term "tobacco product" means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

* * *

21 U.S.C. § 387a – FDA authority over tobacco products.

* * *

(b) Applicability

This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter. This subchapter shall also apply to any tobacco product containing nicotine that is not made or derived from tobacco.

* * *

21 U.S.C. § 387j – Application for review of certain tobacco products.

(a) In general

(1) New tobacco product defined

For purposes of this section the term "new tobacco product" means--

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless--

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product--

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product--

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

* * *

(b) Application

(1) Contents

An application under this section shall contain--

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of

such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

* * *

(c) Action on application

* * *

(2) Denial of application

The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that--

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and

there is a lack of adequate information to justify the deviation from such standard.

* * *

(4) Basis for finding

For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account--

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action

(A) Investigations

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) Other evidence

If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

21 U.S.C. § 387*l* – Judicial review.

(a) Right to review

(1) In general

Not later than 30 days after--

(A) the promulgation of a regulation under section 387g of this title establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 387j(c) of this title,

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

* * *

(b) Standard of review

Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of Title 5 and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of Title 5.

* * *

21 C.F.R. § 10.75 – Internal agency review of decisions.

(a) A decision of an FDA employee, other than the Commissioner, on a matter, is subject to review by the employee's supervisor under the following circumstances:

(1) At the request of the employee.

(2) On the initiative of the supervisor.

(3) At the request of an interested person outside the agency.

(4) As required by delegations of authority.

(b)(1) The review will be made by consultation between the employee and the supervisor or by review of the administrative file on the matter, or both. The review will ordinarily follow the established agency channels of supervision or review for that matter.

* * *

(d) Internal agency review of a decision must be based on the information in the administrative file. If an interested person presents new information not in the file, the matter will be returned to the appropriate lower level in the agency for reevaluation based on the new information.

* * *

21 C.F.R. § 1114.9 – Amendments.

(a) General. FDA may request, or an applicant may submit on its own initiative, an amendment to a [premarket tobacco application] containing information that is necessary for FDA [to] complete the review of a pending [premarket tobacco application]. . . .

* * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2014–N–0189]

RIN 0910–AG38

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to deem products meeting the statutory definition of ''tobacco product,'' except accessories of the newly deemed tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. With this final rule, FDA is extending the Agency's ''tobacco product'' authorities in the FD&C Act to all other categories of products that meet the statutory definition of ''tobacco product'' in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of ''covered tobacco products'' to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. FDA is taking this action to reduce the death and disease from tobacco products. In accordance with the Tobacco Control Act, we consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

DATES: This rule is effective August 8, 2016. See section IV of this document regarding compliance dates for certain provisions.

FOR FURTHER INFORMATION CONTACT: Gerie Voss or Katherine Collins, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 877–287–1373, *AskCTP@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

distributed for retail sale after 30 days following the effective date);

- After the effective date, a distributor or retailer may not sell, offer to sell, distribute, or import for sale or distribution within the United States any such product the package of which does not comply with this regulation, unless the covered tobacco product was manufactured prior to the effective date; and
- After the effective date, however, a retailer may sell covered tobacco products in packages that do not have a required warning if the retailer demonstrates it falls outside the scope of this rule as described in 21 CFR 1143.3(a)(3) and 1143.5(a)(4).

Compliance Policy for Premarket Review—Manufacturers of newly deemed products that are ''new tobacco products'' as defined in section 910(a)(1) of the FD&C Act will be required to obtain premarket authorization of their products through one of three pathways—SE., exemption from SE., or premarket tobacco product applications (sections 905 and 910 of the FD&C Act). As stated in the NPRM, we understand that, for some newly deemed tobacco products, particularly novel products, there may not be appropriate predicate products that were on the market on February 15, 2007, to support a SE claim. Accordingly, in the NPRM, FDA contemplated a compliance period of 24 months after the effective date of the final rule for the submission of applications for all newly deemed, new tobacco products under all three marketing pathways—premarket tobacco applications (PMTAs), SE reports, and SE exemption requests.[2]

FDA carefully considered numerous comments regarding the contemplated compliance period. Many comments expressed concern that newly deemed, new tobacco products would remain available and could continue to be marketed indefinitely without scientific review. Other comments expressed concern, and some submitted data, regarding the effect that flavors have on youth and young adult use of tobacco products. FDA also received comments and data regarding the potential for some net public health benefits that could accrue if flavored ENDS remain available. After carefully considering all of these comments, FDA here announces a revised compliance policy as well as the final rule. (Agency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking. *Prof'ls & Patients for Customized Care* v. *Shalala,* 56 F.3d 592 (5th Cir. 1995) (a compliance policy guide is not a substantive rule and not subject to the Administrative Procedure Act's (APA) notice-and-comment rulemaking); *Takhar* v. *Kessler,* 76 F.3d 995, 1002 (9th Cir. 1996) (FDA compliance policy guides were not required to go through notice-and-comment procedures). But because the relevant time periods are of obvious interest, FDA laid out its anticipated compliance policy in the NPRM, and for similar reasons, is announcing its revised compliance policy here, rather than in a separate guidance document.) As a result of FDA's compliance policy, we expect that many manufacturers will keep their products on the market beyond the effective date of this final rule. However, if a manufacturer of a product is unable to support an SE claim for its product (*e.g.,* is unable to identify a valid predicate, or does not submit an SE report with a valid predicate within the compliance period, or does not receive authorization within a continued compliance period) and does not obtain authorization under one of the other available marketing pathways before the end of an applicable compliance period, such products remaining on the market will be subject to enforcement (*e.g.,* seizure, injunction) for failure to have a marketing authorization under sections 905 and 910 of the FD&C Act.

FDA's NPRM included detailed requests for comments on different possible compliance policy approaches. 79 FR at 23175–77. FDA received many comments on these compliance-policy issues. For example, comments jointly submitted by 24 health and medical organizations stated that the contemplated 24-month compliance period and indefinite period of continued marketing during FDA review included in the NPRM would prolong the public's exposure to products that contain nicotine, a highly addictive substance, and that do not meet the statutory standard for the grant of a marketing order (Comment No. FDA–2014–N–0189–79772.). They stated that this approach would allow manufacturers to market the newly deemed products in ways that appeal to youth and to manipulate the content of these products in uncontrolled ways for an indefinite period (id.). Ranking minority members of the Energy and Commerce Committee, Health Subcommittee, and Oversight and Investigations Subcommittee, U.S. House of Representatives also called for a more protective compliance period than the one contemplated in the NPRM, arguing that the proposed compliance period ''puts the nation's youth at risk'' (Comment No. FDA–2014–N–0189–80119). Further, a network of tobacco control policy and legal specialists expressed concern regarding the effect of continued marketing of tobacco products that have not been reviewed under the applicable public health standards of the Tobacco Control Act (Comment No. FDA–2014–N–0189–81044). FDA also received comments suggesting that the agency should stagger the compliance periods for different product classes based on the continuum of risk, with ENDS having a longer compliance period than other product classes (*e.g.,* Comment No. FDA–2014–N–0189–81859; Comment No. FDA–2014–N–0189–10852). FDA also received comments and new data regarding the effect of flavored tobacco products on youth and young adult use.

FDA understands that the appeal of flavors and use of flavored tobacco products have an important role in the initiation and continued use of tobacco products, and in the health risks associated with use of these products. Based on all of these comments, we have determined that exercising enforcement discretion indefinitely could put youth and young adults at risk for tobacco-related death and disease. However, we recognize that the availability of alternatives to traditional tobacco flavors in some products (*e.g.,* ENDS) may potentially help some adult users who are attempting to transition away from combusted products. Furthermore, at least some flavored combusted products are likely to be ''grandfathered'' and therefore would remain on the market regardless of the compliance period provided in the preamble. Taking into consideration all of the comments on the compliance period and flavors, we are establishing staggered compliance periods. This approach will enable FDA to balance concerns regarding the extended availability of all newly deemed, new tobacco products without scientific review, concerns regarding flavored tobacco products' appeal to youth, and emerging evidence that some adults may potentially use certain flavored tobacco products to transition away from combusted tobacco use. FDA is establishing staggered initial compliance periods based on the expected complexity of the applications to be submitted, followed by continued

[2] Although the NPRM did not explicitly include SE exemption requests as one of the marketing pathways that applicants could utilize within a compliance period, FDA did intend for its contemplated 24-month compliance period to be available for all marketing pathways.

compliance periods for FDA review such that our exercise of enforcement discretion will end twelve months after each initial compliance period. In other words, manufacturers of all newly deemed, new tobacco products will have a 12-, 18- or 24-month initial compliance period in which to prepare applications for marketing authorization, as well as a 12-month continued compliance period after those dates in which to obtain authorization from FDA (resulting in total compliance periods of 24, 30, or 36 months). After the close of the continued compliance period, products will be subject to enforcement unless they are grandfathered or are the subject of a marketing authorization order. FDA's revised compliance policy for premarket review—resulting in products remaining on the market while manufacturers seek review but also contemplating an end to the continued compliance policy—will balance the public health concerns raised in the comments, allow the Agency to more efficiently manage the flow of incoming applications, and encourage high-quality premarket submissions from applicants.

According to this revised compliance policy, for newly deemed products that are on the market on the effective date of this final rule and were not on the market on February 15, 2007, FDA is providing a 12-month initial compliance period for manufacturers to submit (and FDA to receive) an SE exemption request, an 18-month initial compliance period for manufacturers to submit (and FDA to receive) SE applications, and a 24-month initial compliance period for manufacturers to submit (and FDA to receive) a PMTA.

If manufacturers submit (and FDA receives) the applications during their respective compliance periods, FDA, for a certain period of time as discussed in the following paragraph, intends to continue the compliance policy and does not intend to initiate enforcement action for these products remaining on the market without FDA authorization.

For newly deemed tobacco products using the SE Exemption pathway, this continued compliance period (*i.e.,* the time during which FDA does not intend to enforce the premarket review requirements) will close 24 months after the effective date of part 1100 of this final deeming rule (*i.e.,*12 months after the 12-month initial compliance period closes for submission and receipt of SE exemption requests). The earlier submission period for the SE exemption pathway is intended to allow the manufacturer time to consider other pathways if the exemption request is denied or if FDA refuses to accept the request if, for example, the application is incomplete. For newly deemed tobacco products using the SE pathway, this continued compliance period will close 30 months after the effective date of part 1100 of this final deeming rule (*i.e.,* 12 months after the 18-month initial compliance period closes for submission and receipt of SE Reports). For newly deemed tobacco products using the PMTA pathway, this continued compliance period will close 36 months after the effective date (*i.e.,* 12 months after the 24-month compliance period closes for submission and receipt of PMTAs). Any such newly deemed tobacco product for which an application under one of the three marketing pathways has not been submitted within 24 months from the effective date of part 1100 of this final deeming rule will not benefit from this continued compliance policy and will be subject to enforcement as of that date. In addition, once the respective continued compliance period ends for products with applications submitted according to this policy, products remaining on the market without premarket authorizations in effect, even if the product has a pending application that was originally submitted by its respective initial compliance deadline set forth previously in this document, will be subject to enforcement. However, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.

Regarding concerns as to the inability to use the SE pathway for certain products, FDA notes that an applicant may use as a predicate any tobacco product commercially marketed in the United States as of February 15, 2007, or previously found substantially equivalent (note that we interpret the phrase ''as of'' February 15, 2007, as meaning that the tobacco product was commercially marketed (other than exclusively in test markets) in the United States on February 15, 2007. If your tobacco product had been commercially marketed in the United States before February 15, 2007, but was not commercially marketed on that date, it is not a grandfathered product and may not be commercially marketed unless you obtain a marketing authorization under section 910 of the FD&C Act).[3] This may possibly include a predicate that is in a different category or subcategory than the new product that is the subject of the SE report. While FDA currently does not have a policy that limits comparisons to the same category, we do see cross-category comparisons as more challenging for an applicant and we may express limitations on such comparisons in the future, if they become warranted as we gain experience regulating newly deemed products. FDA also is continuing to research e-cigarettes, other ENDS, and heated cigarette products that likely were on the market ''as of'' (*i.e.,* on) February 15, 2007. Additionally, FDA has determined that some e-cigarettes and other ENDS were manufactured in 2006 and commercially marketed in the United States in early 2007. In particular, we have identified an ENDS product that may have been on the market on February 15, 2007. This product may possibly be able to serve as a valid predicate for purposes of the SE pathway. The burden of demonstrating that a valid predicate exists rests with the manufacturer submitting a SE report. To facilitate the determination that a product is eligible to serve as a valid predicate, any individual who has evidence that an e-cigarette or other ENDS was commercially marketed in the United States on February 15, 2007, may submit a stand-alone grandfather submission to FDA (See final guidance, ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (79 FR 58358, September 29, 2014)). (Based on FDA's experiences to date, and since stand-alone grandfather submissions are purely voluntary, FDA does not anticipate that many manufacturers will make such submissions, but this option is available.) Regardless of the predicate selected for comparison, manufacturers are responsible for providing scientific data adequate to demonstrate that, in the case of an SE report, the characteristics of the new product are the same as the predicate or, if the characteristics are different, that these differences do not cause the new product to raise different questions of public health. We encourage interested parties to review the applications FDA

[3] FDA Guidance states that ''[i]f you cannot provide documentation specifically dated on February 15, 2007, FDA suggests you provide documentation of commercial marketing for a reasonable period of time before and after February 15, 2007.'' Guidance for Industry entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (79 FR 58358, Sept. 29, 2014), The guidance also provides examples of sources of evidence, *e.g.,* bills of lading.

NPRM, arguing that the proposed compliance period ''puts the nation's youth at risk'' (Comment No. FDA–2014–N–0189–80119). These comments, among others, all stressed the attractiveness of these newly deemed tobacco products to youth and young adults and the need for a more restrictive compliance policy to ensure that FDA limits the continued marketing of new tobacco products that have not been reviewed under the public health standards of the Tobacco Control Act.

Further, in response to FDA's requests for comments and data in the NPRM, numerous comments included data, research, and personal stories regarding the impact of candy and fruit flavors in tobacco products, including their appeal to youth and young adults, youth perceptions of flavored tobacco products, and their potential effect on transition from combusted tobacco product use (particularly, comments noted, in the case of adults using flavored ENDS to attempt to switch completely away from cigarette smoking). In addition, many comments urged FDA to take immediate action regarding flavored tobacco products as a result of increasing prevalence of flavored product use, and new data show continued growth in youth and young adult usage of flavored tobacco products.

In deciding upon a compliance policy to announce with this final rule, FDA considered all these comments and sought to balance the Agency's concern about the continued marketing of new tobacco products that have not been reviewed by FDA, the potential harmful impact of flavored tobacco products on youth, and the possibility that some of those products are playing a role in helping some tobacco users transition away from what is likely the most harmful form of nicotine delivery for an individual user, combusted tobacco products. FDA considered adopting the compliance policy as described in the preamble to the NPRM or a compliance policy that would provide different compliance periods for flavored and non-flavored tobacco products. FDA also considered providing different compliance periods for different product categories. For example, certain industry comments urged FDA to stagger compliance dates for different product categories, to delay compliance until FDA publishes a final guidance for each product category and to provide ENDS manufacturers a lengthier compliance period based on where they purport to fit within the risk continuum for nicotine-delivering products (*e.g.,* Comment No. FDA–2014–N–0189–81859; Comment No. FDA–2014–N–0189–10852).

In response to these comments, we note that nicotine use in any form is of particular concern for youth and pregnant women. On the other hand, some evidence suggests that ENDS may potentially promote transition away from combusted tobacco use among some current users and it is possible that there could be a public health benefit. See also section III.F for additional discussion of premarket pathways and the continuum of nicotine-delivering products. Based on currently available scientific evidence, this revised compliance policy strikes an appropriate balance among various, often competing, considerations.

2. FDA Is Announcing a Revised Compliance Policy With Staggered Timeframes and Continued Compliance Periods

In the interest of public health and taking into account the fact that there are products already on the market that will now be subject to premarket review, and in light of the considerations discussed in section 1 above, we have established the following compliance policy for newly deemed tobacco products. For those newly deemed products that were on the market on the effective date of this final rule, but that were not on the market on February 15, 2007, FDA is providing two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. Although such products are subject to the premarket review requirements of the FD&C Act, FDA does not intend to initiate enforcement action for failure to have premarket authorization during the respective compliance periods.

The compliance period for submission and FDA receipt of applications for newly deemed tobacco products under the three premarket pathways is as follows:

SE Exemption Requests—12 months from the effective date of this final rule

SE Reports—18 months from the effective date of this final rule

PMTAs—24 months from the effective date of this final rule

FDA is adopting the staggered timelines in this policy to account for the possibility that applicants may need additional time to gather information for certain premarket submissions that may require additional data. For example, if a manufacturer plans to submit an SE Exemption Request, the firm may only need to identify the product, provide certification statements, and gather scientific information on the additive change itself and any supporting information demonstrating that the change to the product is minor and an SE Report is not necessary. This is less information than that likely required for a PMTA. We expect this policy will also create a more manageable flow of premarket applications for newly deemed products. FDA expects that this staggering of deadlines also will benefit regulated industry, since it will allow for greater efficiency of FDA review and incentivize higher quality applications, which will reduce review times for all products. New products for which no application has been submitted by 24 months from the effective date of this rule will no longer be subject to this compliance policy and will be subject to enforcement.

Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period, which is as follows:

SE Exemption Requests—24 months from the effective date of this final rule (12 months after the compliance period for submission of such requests)

SE Reports—30 months from the effective date of this final rule (12 months after the compliance period for submission of such reports)

PMTAs—36 months from the effective date of this final rule (12 months after the compliance period for submission of such requests).[13]

Once the continued compliance period ends, new tobacco products on the market without authorization will be subject to enforcement. FDA will act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. FDA expects that this revised compliance policy will encourage the submission of high quality applications. By providing a date in which the continued compliance period ends, manufacturers will have an incentive to submit a complete application and respond substantively and expeditiously to questions raised during the review process instead of an incomplete or deficient application just to stay on the market indefinitely. This staggered

[13] In addition, we note that any new tobacco product that was not on the market on the effective date of the rule (*i.e.,* 90 days after the publication date) is not covered by this compliance policy and will be subject to enforcement if marketed without authorization after the effective date.

the total for each type of transaction in which they engaged.

(i) *Voluntary reporting of insurance transactions.* If, during calendar year 2018, total transactions were $2 million or less in each of the insurance categories covered by the survey, on an accrual basis, the U.S. insurance company may, in addition to providing the required total for each type of transaction, voluntarily report transactions at a country and affiliation level of detail on the applicable mandatory schedule(s).

(ii) [Reserved]

(3) *Exemption claims.* Any U.S. person that receives the BE–140 survey form from BEA, but is not subject to the reporting requirements, must file an exemption claim by completing the determination of reporting status section of the BE–140 survey and returning it to BEA by the due date of the survey. The requirement in this paragrpah (b)(3) is necessary to ensure compliance with reporting requirements and efficient administration of the Act by eliminating unnecessary follow-up contact.

(d) *Covered types of insurance services.* Insurance services covered by the BE–140 survey consist of transactions between U.S. insurance companies and foreign persons for:

(1) Premiums earned on reinsurance assumed from companies resident abroad;

(2) Losses incurred on reinsurance assumed from companies resident abroad;

(3) Premiums paid for reinsurance ceded to companies resident abroad;

(4) Losses recovered on reinsurance ceded to companies resident abroad;

(5) Premiums earned from direct insurance sold to foreign persons;

(6) Losses incurred on direct insurance sold to foreign persons;

(7) Receipts for auxiliary insurance services provided to foreign persons; and

(8) Payments for auxiliary insurance services provided by foreign persons.

(e) *Types of transactions excluded from the scope of this survey.* Premiums paid to, or losses received from, foreign insurance companies on direct insurance.

(f) *Due date.* A fully completed and certified BE–140 report, or qualifying exemption claim with the determination of reporting status section completed, is due to be filed with BEA not later than September 30, 2019.

[FR Doc. 2019–12373 Filed 6–11–19; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2015–D–2496]

Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry." Given the relatively new presence of electronic nicotine delivery systems (ENDS) on the U.S. market and FDA's final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA expects to receive premarket tobacco product application (PMTA) submissions from manufacturers of ENDS. This guidance is intended to assist applicants to prepare PMTAs for ENDS products.

DATES: The announcement of the guidance is published in the **Federal Register** on June 12, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2015–D–2496 for "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access

the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–CTP–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems.''

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the FD&C Act and granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Under section 901(b) of the FD&C Act (21 U.S.C. 387a(b)), FDA's tobacco product authorities in chapter IX of the FD&C Act apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to chapter IX. On May 10, 2016, in the **Federal Register**, FDA published its final rule, ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (Deeming rule) extending FDA's tobacco product authority to ENDS, among other products (81 FR 28973). In the same issue of the **Federal Register**, FDA concurrently announced the availability of the draft guidance, ''Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request'' (81 FR 28781). FDA received comments on the draft guidance and those comments were considered as the guidance was finalized. Changes made as a result of public comments include recommendations for constituent testing, single applications for new tobacco products that an applicant intends to market as a modified risk tobacco product, and the number batches and replicates related to product testing.

Under section 910 of the FD&C Act (21 U.S.C. 387j), persons seeking to market a new tobacco product (as defined in section 910(a)(1) of the FD&C Act) must first submit a PMTA to FDA and obtain a marketing authorization order, unless FDA has issued an order that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or the new tobacco product is exempt from demonstrating substantial equivalence pursuant to the reasons outlined in section 905(j)(3) of the FD&C Act (21 U.S.C. 387e(j)(3)). ENDS products, the subject of this guidance, likely would be considered new tobacco products. Given the relatively new presence of ENDS on the U.S. market, FDA anticipates that many manufacturers of these new tobacco products will seek a marketing authorization order by filing a PMTA. This guidance explains, among other things, when a PMTA is required, general procedures for review of an ENDS PMTA, what information the FD&C Act requires applicants to submit in a PMTA, and what information FDA recommends applicants submit in an ENDS PMTA to show whether permitting such new tobacco product to be marketed is appropriate for the protection of the public health.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on PMTAs for ENDS. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 1107.1 have been approved under OMB control number 0910–0768.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance.*

Dated: June 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12389 Filed 6–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 171

[Docket ID: DOD–2018–OS–0051]

RIN 0790–AK42

Wildfire Suppression Aircraft Transfer Act of 1996

AGENCY: Office of the Assistant Secretary of Defense for Sustainment, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the DoD regulation which implemented law authorizing the sale of aircraft and aircraft parts to entities that contract with the Federal government for the delivery of fire retardant by air in order to suppress wildfire. This authorization has since expired. Existing statutory authorities allow the sale or transfer of aircraft and aircraft parts to Fire Fighter

submit an environmental assessment under part 25 of this chapter.

(d) *Disclosure of data and information after issuance of an order under § 1107.48.* After FDA issues an order under § 1107.48 (denying marketing authorization), FDA may make certain information related to the SE Report and the order available for public disclosure upon request or at FDA's own initiative except to the extent the information is otherwise exempt from disclosure under part 20 of this chapter. Information FDA may disclose includes the tobacco product category (*e.g.,* cigarette), tobacco product subcategory (*e.g.,* filtered), package size, and the basis for the order denying marketing authorization.

(e) *Health information summary or statement.* Health information required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, if submitted as part of the SE Report (which includes any amendments), will be disclosed within 30 calendar days of issuing a substantially equivalent order. If the applicant has instead submitted a 910(a)(4) statement as provided in § 1107.18(j)(2), FDA will make publicly available on FDA's website the responsible official to whom a request for health information may be made.

§ 1107.62 Electronic submission.

(a) *Electronic format requirement.* Applicants submitting any documents to the Agency under this part must provide all required information to FDA using the Agency's electronic system, except as provided in paragraph (b) of this section. The SE Report and all supporting information must be in an electronic format that FDA can process, read, review, and archive.

(b) *Waivers from electronic format requirement.* An applicant may submit a written request that is legible and written in English, to the Center for Tobacco Products asking that FDA waive the requirement for electronic format and content. Waivers will be granted if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants can send the written request to the address included on our website (*www.fda.gov/tobaccoproducts*). The request must include the following information:

(1) The name and address of the applicant, list of individuals authorized for the applicant to serve as the contact person, and contact information including an email address. If the applicant has submitted an SE Report previously, the regulatory correspondence must also include any identifying information for the previous submission.

(2) A statement that creation and/or submission of information in electronic format is not reasonable for the person requesting the waiver, and an explanation of why creation and/or submission in electronic format is not reasonable. This statement must be signed by the applicant or by an employee of the applicant who is authorized to make the declaration on behalf of the applicant.

(c) *Paper submission.* An applicant who has obtained a waiver from filing electronically must send a written SE Report through the Document Control Center to the address provided in the FDA documentation granting the waiver.

Dated: September 21, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2021–21009 Filed 10–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1107 and 1114

[Docket No. FDA–2019–N–2854]

RIN 0910–AH44

Premarket Tobacco Product Applications and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, us, or we) is issuing a final rule that sets forth requirements for premarket tobacco product applications (PMTAs) and requires manufacturers to maintain records establishing that their tobacco products are legally marketed. The rule will help ensure that PMTAs contain sufficient information for FDA to determine whether a marketing granted order should be issued for a new tobacco product. The rule codifies the general procedures FDA will follow when evaluating PMTAs and creates postmarket reporting requirements for applicants that receive marketing granted orders. The rule also requires tobacco product manufacturers to keep records establishing that their tobacco products are legally marketed, such as documents showing that a tobacco product is not required to undergo premarket review or has received premarket authorization.

DATES: This rule is effective November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Office of Regulations, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total	.....	.....	.....	.....	13,540

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] FDA anticipates that applicants will submit bundled PMTAs, which are single submissions containing PMTAs for a number of similar or related products. We estimate that a bundle will contain on average (between 6 and 11) with most submitting 9 distinct products.

FDA has based these estimates on the full analysis of economic impacts and experience with current PMTA submissions. Table 1 describes the current estimates for OMB control number 0910–0768 which covers the burden for ENDS products PMTA submissions. These estimates were originally published in the deeming final rule and recently in the **Federal Register** of April 22, 2019 (84 FR 16673). FDA estimates that it will take each respondent approximately 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours to prepare an EA in accordance with the requirements of § 25.40, for a total of 1,713 hours per PMTA application.

Table 1 describes the estimated annual reporting burden per the requirements that the rule would create beyond what is covered in the existing information collection. For this analysis, FDA assumes that firms will submit all applications as PMTA bundles. We also considered updated data on market consolidation that has occurred since the deeming final rule was published. For originally regulated products we expect to receive one full PMTA submission for a total of 1,713 hours.

FDA conducted a thorough analysis of the current paperwork burden associated with the PMTA program and other similar forms and applied the most accurate burden to the forms; however, upon further review and certain updates made to the form based on comments received and product categorization changes, FDA has revised the burden associated with entering the data into the form (which includes searching existing data sources and gathering and maintaining the data needed) to be 45 minutes per individual product (rather than 30 minutes per product) on Form FDA 4057. For Form FDA 4057a, FDA has revised the burden for this form to 10 minutes (from 5 minutes). This form serves several purposes from changing a point of contact (minimal burden) to providing additional substantive information for the purpose of the review of the PMTA application (more burdensome).

FDA developed Form FDA 4057 for use when submitting PMTA single and bundled submissions. FDA estimates that 24 respondents will submit PMTA bundles using this form at 0.75 (45 minutes) per response. The number 24 is accounting for the bundles of ENDS products and the 1 bundle we expect to receive yearly for originally regulated products. (200 + 1 = 201/8.5 products on average in a bundle) for a total of 12 hours.

FDA developed Form FDA 4057a for use when firms are submitting amendments and other general correspondence. Our estimate is 0.16 (10 minutes) per response to fill out this form. We estimate there will be at least one amendment per application for a total of 28 hours. With most applications being submitted toward the end of our 3-year range, we expect fewer amendments during this period. However, FDA expects correspondence from earlier applications to be submitted during this period.

FDA developed an additional form (Form FDA 4057b) that will assist industry and FDA in identifying the products that are the subject of a submission where an applicant groups multiple PMTAs into a single submission (referred to as a bundled submission or a grouped submission). FDA has previously stated that one approach to submitting PMTAs could be to group applications for products that are both from the same manufacturer or domestic importer and in the same product category and subcategory into a single submission. FDA discussed bundled submissions in the proposed rule (84 FR 50566 at 50578) and noted that FDA intends to consider information on each tobacco product as a separate, individual PMTA. The form will assist applicants in providing the unique identifying information for each product in a grouped submission of PMTAs that are required § 1114.7(c)(3)(iii). By having the identifying information for products contained in a submission be more clearly organized, FDA will be able to more efficiently process and review the applications contained in a grouped submission.

Based on the Form FDA 4057 for use when submitting PMTA single and bundled submissions, a respondent would utilize Form FDA 4057b once for each submission containing more than one PMTA. We assume the submitter could include from 2 to 2,000 products in each Form FDA 4057b. Entering data for up to 2,000 rows can take approximately 4 hours on average per Form FDA 4057b for manual data entry. However, FDA's original estimate that Form 4057b would estimate 4 hours per response was a high-end estimate and not an average. We now reflect the average time of 45 minutes per response based on the assumption that we expect to receive an average of nine bundled products per submission. Assuming 45 minutes per Form FDA 4057b for 24 applications, we estimate a total burden of 18 hours for this activity.

FDA estimates under § 1114.41 that three respondents will submit a periodic report. This number is based on the average number of periodic report submissions expected between 2020–2022. The RIA estimates that periodic reports will take between 20 and 80 hours per submission. For this estimate, we use the average of 50 per response for a total of 150 hours.

Under § 1114.9 firms will prepare amendments to PMTA bundles in response to deficiency letters. These amendments contain additional information that we need to complete substantive review. In the RIA we state in our limited history reviewing PMTAs, we on average issue two deficiency letters. Based on this, we would anticipate two responses back per bundle. Therefore, we estimate that 24 respondents will submit 48 amendments (24 × 2). Assuming 1,500 hours as the time to prepare and submit a full PMTA and amendments may on average take 10 percent to 15 percent of that time (150–225). We averaged this time out (12.5 percent of a full submission preparation time) and arrived at 188 hours per response. FDA estimates the total burden hours for preparing amendments is 9,024 hours.